Development Committee Meeting Notes, May 22, 2007

To	Furter Rolf CHBS; Barnes Jasper CHBS; Brady Angela CHBS; Brown Richard Anthony CHBS; Gehmann Klaus Bernd CHBS; Gordon Paul Francis CHBS; Ramos Gerardo CHBS; Suter Jan Martin CHBS	Date:	22.05.2007
		Copy Mgmt:	Lawrence David CHBS; Atkin John CHBS; Berendes Robert CHBS; Rezende Maercio CHBS; Pisk Davor SGSG; Fischer Valdemar USGR; Guimaraes Antonio BRSP; Doe John GBAP; Doppmann Franz CHBS; Diriwaechter Georg CHBS; Dalton Ian Paul SGSG; Dickson Gary USGR; Gallina Fernando BRSP; Sozzi Dino CHBS
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Location:	**Meeting Room: WRO 1007.8.46**		
Time:	**1300-1800**		

Dear DeCo Members

Attached you find the minutes of the meeting on May 22, 2007. All presentations have been posted to the **DeCo TeamSpace**: http://ts1.pro.intra/sites/GRDDeCo/default.aspx

With best regards

Jasper Barnes

Notes

Topic
1. **Regulatory options to support Inteon submissions globally** ((Ball Christopher CHBS; Dieterle Roland CHBS; McFarland Janis USGR; Dias Andre CHBS; Elliott Barry GBAP) – **Summary and Recommendations**

There are currently no issues in replacing existing Gramoxone with Inteon based products. The major challenge is to obtain a safety standard or an improved toxicology classification for Inteon products.

- With the current dataset it can be demonstrated that Inteon formulations lead to safer products, but with the complexity of Gramoxone formulations globally (strength, emetic, alerting agent etc.) it is very difficult to have a straight forward comparisons with all products. Therefore, we risk that authorities may ask for additional data to demonstrate 'Proof of Concept'. 3 additional studies are proposed for PoC to demonstrate effect of increased emetic level, the purgative, and the whole Inteon technology at a defined strength.
- In the US, EPA have questioned if Inteon technology is needed for safer products or if 3X emetic is sufficient. Until this question is resolved, they have granted time-limited registrations to generic companies for 3X emetic formulations. Syngenta have submitted historical studies demonstrating that 5X emetic only provides limited safening, but EPA remain unconvinced and require more specific answers on formulation components providing improved safening.
- Without an additional dog study with the 360 g/l non-Inteon at 3X emetic formulation, the US Product Registration Team see no chance of obtaining a safety standard. This study is needed with high priority to allow EPA a quick data review and decision to revoke the time-limited registrations by ca. Sep 08, or in the worse case, 12 to 18 months later. However, there is no guarantee from EPA that this study will be sufficient to ensure a safety standard.
- In Japan, the current Gramoxone formulations have a dokubutsu classification by default; however, the current Preeglox L and the Inteon 100 g/l principally qualify for the lower gekibutsu classification. To achieve this classification we need to demonstrate a significantly improved toxicology profile with the Inteon 100 g/l product. Existing studies were conducted with a non-emeticised Preeglox L and Japanese Inteon to a limited dose, which may not be sufficient for the authorities to grant gekibutsu. Our approach is to use available dog studies and to extrapolate data to current Preeglox L. If our argumentation fails, we should conduct additional dog studies for Japan.
- Regulatory options:
  - **Option 1**: Do no additional studies
  - **Option 2:** Mandatory studies to get a safety standard in US
    1. Gramoxone Max 360 g/l at 3X emetic levels
  - **Option 3:** Mandatory studies to get US standard and Global Proof of Concept studies;
    1. Gramoxone Max 360 g/l at 3X emetic levels
    2. 240 g/l Inteon (A7318K) without alginate or purgative at 1X emetic
    3. 240 g/l Inteon without alginate or purgative at 3x emetic
    4. 240 g/l Inteon without alginate at 3X emetic
    5. Preeglox L baseline study for Japan
    6. Inteon A9409AM for Japan

    Studies 5 and 6 are contingency studies and will only be carried out if our argumentation to get gekibutsu fails
- **Option 1** is commercially and from regulatory point of view not acceptable. 0% chance to get a standard in US and negative impact to get a standard in RoW (why does US not set a standard)
- **Option 2** will partially address EPA's concerns and allow a 75% chance of obtaining the safety standard. Low risk of generation of non-fitting data, moderate risk that EPA requests further information on other safening agent effects and ratios. The cost would be $150 – 175k.
- **Option 3** will offer a >75% chance to get a safety standard in US and may positively impact the setting of standards in RoW (ACC, Mexico, Taiwan). Improved chance to get a gekibutsu classification in Japan. Low risk of obtaining non-fitting data, low risk that EPA may request additional data. There's a moderate risk that improvement in safety of Japanese Inteon is not sufficient. Syngenta possession of a comprehensive high quality dataset is viewed to be a door opener with regulatory authorities across the world. The cost of Option 3 is $650k + 300-350k contingency.

3 **Recommendation**

- The MPT request the approval for Option 3 which consists of 1 mandatory study for EPA, 3 Proof of

Communication Plan

The DeCo approved the MPTs request for Option 3 at max. costs of approx. $1m.

- The new studies commissioned for paraquat formulations will enable Syngenta to answer the outstanding questions from EPA and improve the chance of obtaining a safety standard for Inteon in the US. The studies also provide a robust data package to support Inteon submissions globally. The setting of a US safety standard will be helpful in supporting other countries to set safety standards. 2 studies to support the re-classification of Inteon in Japan are planned as contingencies.

Actions and Next Steps	Responsible	Deadline	Status
Develop study plan priorities for 2007 and 2008.	Dieterle Mario Roland CHBS; Elliott Barry GBJH	July 2007	On-going
Discuss targeted internal communication for releasing results of emetic studies with Andre Dias and David French.	Barnes Jasper CHBS	End-July 2007	

Introduction, review of minutes from meeting

SYN520453: recommendation for EU Rapporteur Member State (Wright Tanya CHBS; Jackson-Gheissari Amelia CHBS; West Jane CHBS) – **Summary and Recommendations**

Key success criteria for choice of a Rapporteur Member State (RMS) for SYN520453 include speed of review, access to a significant cereal market in the first year of sales, desire to have an ongoing dialogue with Syngenta before and during the review process, willingness to work with notifier & EFSA to set t-MRLs quickly to allow national provisional approval.

- Four countries were considered to be frontrunners for RMS for SYN520453: UK, Germany, Austria and France.
- France was considered, but not selected due totheir internal re-organization and relocation has led to delays in reviewing dossiers and speed to market is critical for SYN520453.
- Syngenta had a very positive experience with Austria in review of mandipropamid but it was felt that their lack of experience with more complex dossiers and the size of the cereal market would not make them the ideal choice for SYN520453.
- Currently Syngenta has met with the Pesticide Safety Directorate (PSD) in the UK and also AGES in Austria. It has not been possible to meet with BVL and UBA, the German authorities, so far.
- PSD have offered to review the dossier in 9 months after the completeness check (time to DAR) and are willing to use SYN520 as a vehicle to try to improve the t-MRL setting process & timelines.
- It is important that a decision regarding RMS for SYN520453 is made quickly to meet the accelerated project timelines.
- In summary, PSD offers our best opportunity for fast review and getting market as quickly as possible in a major cereal market. The project team makes the recommendation that the DeCo supports this recommendation so that PSD can be informed of the decision and Syngenta can start working with them as quickly as possible.

Communication Plan

- Following a thorough review of EU Rapporteur Member States (RMS) the 520 project team recommends that the Pesticide Safety Directorate (PSD) is appointed to review the 520 dossier.
- Syngenta will work with PSD before and during review to ensure that the fastest timelines are achieved.
- The SYN520453 MPT will communicate that the UK PSD has been selected as the Rapporteur Member State.

Actions and Next Steps	Responsible	Deadline	Status
Inform PSD of Syngenta's decision to accept their proposal for review of the SYN520453 dossier	West Jane CHBS	May 2007	
Organise kick-off meeting with PSD experts to introduce them to SYN520453	West Jane CHBS	June/July 2007	

Celest Multi - Release to first Sales: Performance the first year of sales (Hansen Anette CHBS; Mittermeier Ludwig CHBS) – **Summary and Recommendations**

Celest Multi was introduced in 2006 in UK under the Beret brand name. Sales reached $46'000 in the first year with significant increase (budget for 2007) to $256'000.

- Product performance was good, but pricing needed adjustment to satisfy margin expectations of distributors.
- Further registrations are expected end 2007/early 2008 for launch in Germany, Lithuania and Hungary in 2008. Timely registrations are particularly critical for Germany as there are no sales of Solitaer in barley anymore (tebuconazole based mixture).
- In France, Celest Multi will not be registrable because of flutriafol restrictions and the alternative will remain Celest Orge Net. Future tebuconazole sources are open and there are ongoing discussions with BSC and MA.
- To exploit rate flexibility 1.5 l/ton vs. full rate of 2 l/ton seed will become critical for commercial success in Italy, Spain and Central European countries like Poland and the Czech Republic.
- The price target of 20$/litre remains a significant challenge and a price review is planned for early 2008 which might require re-negotiation on supply price for flutriafol with Cheminova.
- Formula M technology, as well as, contribution of Fludioxonil to mycotoxin management in cereals will be main differentiation factors to competitors.
- Total sales forecast (Sympact 2006) for Celest Multi are at 12 mio$ in 2010 vs 9.5 mio$ expected at the release to first sales in May 2006.

Actions and Next Steps	Responsible	Deadline	Status
Assure good data base re rate flexibility (U. nuda)	Hansen Anette CHBS;	3Q/2008	
1. Review pricing	Mittermeier Ludwig CHBS	1Q/2008	
Potential re-negotiation of flutriafol supply price	Brandl Franz CHBS	2Q/2008	

P000008-03: PPM: Optigard Ant Gel Bait development for C&C use (A15236A, A15277A, USA); Release to First Sales (Yoder Joe USGR; Parshley Tom USGR; Zajac Mark USGR; Willenbrock Pat USGR) – **Summary and Recommendations**

Summary

- US General Pest Control market valued at $172 mio (ex-mfr) in 2006
- Highly fragmented with specialized brands and SKUs; over 90 brands for ants alone.
- Optigard Ant Gel Bait second product in Optigard brand family
- Several others planned, most with good potential for extension into DIY consumer markets
  - Optigard Roach Bait (2008)
  - Label extension for Optigard ZT (2008)
  - Others in various planning phases
- Key Economic Figures
  - Year 1st Sales – 2007
  - Max Sales - $1mio
  - Years to Max Sales – 3
  - %GM – 60%
- Key Benefits
  - Superior matrix and formulation:
    1. Clear
    2. Colorless
    3. Odorless
    4. Labeled for indoor and outdoor use in cracks and crevices
  - Optigard Ant Gel Bait provides control of broad range of ant species (workers and queen), superior to Maxforce, the industry standard
- Product Description
  - 30g syringe; 4 syringes per box
  - Priced on par with DuPont Advion (indoxacarb) and Bayer MaxForce FC Select (fipronil)
    1. Price to PMP end user, $6.00/syringe
    2. Price to distributor $4.80/syringe
- Regulatory Summary
  - Product initially approved in USA 04-Apr-2007
  - Language for label claims required some negotiations after registration
  - Label quickly amended and approved by EPA after negotiations on 02-May-2007
- SWOT

Communication Plan

Summary

- Optigard Ant Gel Bait second product in Optigard brand family
- Several others planned, most with good potential for extension into DIY consumer markets
- Optigard Roach Bait (2008)
- Label extension for Optigard ZT (2008)
- Others in various planning phases
- Key Benefits
  - ➢ Superior matrix and formulation:
    1. Clear
    2. Colorless
    3. Odorless
- Labeled for indoor and outdoor use in cracks and crevices
- Superior efficacy and spectrum
- Optigard Ant Gel Bait provides control of broad range of ant species (workers and queen), superior to Maxforce, the industry standard

Actions and Next Steps	Responsible	Deadline	Status
USA and Global Business and Development teams to be informed of DeCo approval for Release to First Sales of Optigard Ant Gel Bait in USA.	Yoder Joe USGR, Willenbrock Pat USGR, Hern Murray CHBS	May 30 2007	

Action list previous meetings

Topic	Action	Meeting	Lead	Due Date	Status
4. Axial EC100 – Formulation shelf-life update	Extend the assessment program of newly manufactured Axial for a further year –	DeCo 22.08.06	Critchley Susan CHBS and focus team	July 2007	Ongoing: Findings will be presented at August DeCo
2. Release to 1st Sales of Mandipropamid (MPD, NOA446510) and its 1st wave formulations (446 solo, 446/CTN, 446/MZ, 446/FP)	Feedback to DeCo following visits to first commercial sprays following launch in large scale use	DeCo 30.11.06	Wright Tanya CHBS;	May 22, 2007 update recommend overall review March 2008	**Solo** has been sprayed extensively in S Korea without problems; **FP mix:** Austria/June 07 **CTN mix**: LATAM Dec 07 MZ mix : 2008
2. Release to 1st Sales of Mandipropamid (MPD, NOA446510) and its 1st wave formulations (446 solo, 446/CTN, 446/MZ, 446/FP)	Obtain (prov.) registrations in DE and UK for sales in 2007 and in all relevant markets according to registration plan	DeCo 30.11.06	Iwanzik Wolfgang CHBS;		In progress
2. Release to 1st Sales of Mandipropamid (MPD, NOA446510) and its 1st wave formulations (446 solo, 446/CTN, 446/MZ, 446/FP)	Launch MPD-products successfully in 2007	DeCo 30.11.06	Hirai Yasuhiro CHBS;	Jul 2007	In progress
2. Release to 1st Sales of Mandipropamid (MPD, NOA446510) and its 1st wave formulations (446 solo, 446/CTN, 446/MZ, 446/FP)	Submit 2nd wave formulations in EAME (446/Cu) and USA (446/DFZ)	DeCo 30.11.06	Iwanzik Wolfgang CHBS;	Jun 2007	In progress
4. OPA SYN 524464 (Seed treatment) - update on plans and timelines	DeCo invites team to continue to evaluate other market opportunities with this product to expand uses and value. The business case and costs for additional uses will be reviewed in 2007.	DeCo 30.11.06	Kelly Tim CHBS + MPT	3Q07	In progress – several new crops to be profiled in 07. OSR not until A/W 07.
5. Quilt A13705L in USA, Canada, South Korea and Saudi Arabia: Update on formulation development status	Continued formulation stability testing, spray tank and compatibility testing	DeCo 30.11.06	Wen Xinyun USGR;	Dec 2007	In progress

Topic	Action	Meeting	Lead	Due Date	Status
5. Quilt A13705L in USA, Canada, South Korea and Saudi Arabia: Update on formulation development status	Continued process robustness, stability and sensitivity testing	DeCo 30.11.06	Cortez Jeff USGR;	Jun 2007	In progress
5. Quilt A13705L in USA, Canada, South Korea and Saudi Arabia: Update on formulation development status	Continued biology testing – the L variant will be a treatment in various protocols during the 2007 season.	DeCo 30.11.06	Tally Allison USGR;	Dec 2007	In progress when 2007 season sprays start
2. Pinoxaden short launch update and A13617R Release for First Sales	Complete Release to First Sales Document for DeCo signoff	DeCo 22.01.07	Ball Christopher CHBS	Feb 2007	In progress, Will be completed for the DeCO by the end of March.
5. Chili 40 WG; Stage C Promotion	Stage D recommendation	DeCo 22.01.07	Molitor Elvira CHBS	Nov 2007	In progress
2. DASH and BISAM Promotions to Stage 2: Plans for 2007	Return to DeCo as required to present results but certainly on 29th November 2007	DeCo 22.02.07	Keith Deborah GBJH; Molitor Elvira CHBS; Ball Christopher CHBS	Nov 2007	In progress
4. P000608-03: Lufenuron New Formulation: Medfly chemosterilant A-14619 A ; Release to first sales	Prepare supply chain for launch in Spain	DeCo 22.02.07	Campbell Jacqui CHBS	Mar 2007	Ongoing
4. P000608-03: Lufenuron New Formulation: Medfly chemosterilant A-14619 A ; Release to first sales	Complete branding and launch plans for Spain	DeCo 22.02.07	Bardon Javier ESMD	April 2007	Branding complete and launch plan with the new Product Manager, Juan Trigos. Internal launch in May/June and external activities to start in September.
4. P000608-03: Lufenuron New Formulation: Medfly chemosterilant A-14619 A ; Release to first sales	Development concept for new use patterns globally	DeCo 22.02.07	Skillman Stephen CHBS	Dec 2007	In progress

Topic	Action	Meeting	Lead	Due Date	Status
4. P000608-03: Lufenuron New Formulation: Medfly chemosterilant A-14619 A ; Release to first sales	Handover process global to region EAME	DeCo 22.02.07	Skillman Stephen CHBS	Dec 2007	In progress
6. P000736-03: ST: Develop Global Corn Formulation FDL/MFX/TBZ/AZ (2.5/2/20/1); Colored (Global); Stage C Promotion	Finalize formulation test re. AI quality and application properties	DeCo 22.02.07	Cush Sarah USGR	Aug 2007	In progress
6. P000736-03: ST: Develop Global Corn Formulation FDL/MFX/TBZ/AZ (2.5/2/20/1); Colored (Global); Stage C Promotion	Data on contribution to mycotoxin mgmt and regulatory support for AZ and increased MFX rate in France	DeCo 22.02.07	Oostendorf Michael PCHBS	Dec 2007	In progress
6. P000736-03: ST: Develop Global Corn Formulation FDL/MFX/TBZ/AZ (2.5/2/20/1); Colored (Global); Stage C Promotion	List of key countries to prioritize global registration	DeCo 22.02.07	Bonfils Marc CHBS	May 2007	In progress
2. AVICTA 400FS (A14024C) as a ST for Nematode control in Vegetables; Release to First Sales:	Strategic launch of AVICTA 400FS in melons/USA	DeCo 19.03.07	Shetty Kiran USGR; Shelton Chad USGR	Nov 2007	In progress
2. AVICTA 400FS (A14024C) as a ST for Nematode control in Vegetables; Release to First Sales:	Formulation variant testing for enhanced biological performance	DeCo 19.03.07	Cochran Alex CHBS	Nov 2007	In progress
2. Gramoxone Inteon Projects Review	Raise paraquat strategy discussion in the CPLT to build the basis for decisions on Inteon Gold and global approach to toxicology studies.	DeCo 18.04.07	Furter Rolf CHBS	May 2007	Completed. The CPLT reviewed the overall PQ outlook, agreed on a very positive scenario which got approved by the SEC on May 15.
2. Gramoxone Inteon Projects Review	How have we challenged the UK PSD decision on cis-3-hexenol? Determine and report back to the DeCo	DeCo 18.04.07	Ball Christopher CHBS; Dieterle Roland CHBS	May 2007	Complete  Action Item Update_2_Gramoxon

Topic	Action	Meeting	Lead	Due Date	Status
2. Gramoxone Inteon Projects Review	Organize a Regulatory/Product Safety Review to prepare for CPLT	DeCo 18.04.07	Dieterle Roland CHBS; Elliott Barry; Ball Christopher CHBS	May 2007	Complete
3. P001366-04: TSS+prometryn [Suprend WG80 A12474D] - Fluowet removal from the A variant; Stage C Promotion:	Confirmation of frozen candidate based on field efficacy results	DeCo 18.04.07	Glasgow Les USGR	Sept 2007	In progress
3. P001366-04: TSS+prometryn [Suprend WG80 A12474D] - Fluowet removal from the A variant; Stage C Promotion:	Package submission to EPA	DeCo 18.04.07	Dixon Monty USGR	Dec 2007	In progress
3. P001366-04: TSS+prometryn [Suprend WG80 A12474D] - Fluowet removal from the A variant; Stage C Promotion:	Release to First Sales	DeCo 18.04.07	Carmean Kurt USGR	Oct 2008	In progress
3. P001366-04: TSS+prometryn [Suprend WG80 A12474D] - Fluowet removal from the A variant; Stage C Promotion:	Pre-production trial at third party toller	DeCo 18.04.07	Davis John USGR	Jan 2009	In progress
4. Graduate A+: Fludioxonil + Azoxystrobin Citrus Post Harvest Formula for Global Use	Compatibility with tank mix partner and continue storage stability testing	DeCo 18.04.07	Wen Xinyun USGR	June 2007	In progress
4. Graduate A+: Fludioxonil + Azoxystrobin Citrus Post Harvest Formula for Global Use	Scale up/ robustness testing	DeCo 18.04.07	Davis John USGR	June 2007	In progress
4. Graduate A+: Fludioxonil + Azoxystrobin Citrus Post Harvest Formula for Global Use	Acute 6-pack completed	DeCo 18.04.07	Tisdel Merrill USGR	Oct 2007	In progress
4. Graduate A+: Fludioxonil + Azoxystrobin Citrus Post Harvest Formula for Global Use	MRLs established	DeCo 18.04.07	Still Kelly USGR	Dec 2009	In progress

Topic	Action	Meeting	Lead	Due Date	Status
5. Aba SC (P000363-05 and P000015-07): Stage C Promotion	Communicate Stage C Promotion to project team and business units	DeCo 18.04.07	Yoder Joe USGR; Wang Jenny CHBS	Apr 2007	Complete
5. Aba SC (P000363-05 and P000015-07): Stage C Promotion	Review for Release to First Sales	DeCo 18.04.07	Yoder Joe USGR;	Mar 2008	In progress
6. P000018-06: ST: Cruiser Maxx Cereals (A15424A, Cruiser/Dividend XL RTA Prepak, CAN, USA, ARG, BRA, Chile); Stage C Promotion	Communicate Stage C Promotion to project team and business units	DeCo 18.04.07	Yoder Joe USGR; Ewert Scott CATO	Apr 2007	Complete
6. P000018-06: ST: Cruiser Maxx Cereals (A15424A, Cruiser/Dividend XL RTA Prepak, CAN, USA, ARG, BRA, Chile); Stage C Promotion	Review for Release to First Sales	DeCo 18.04.07	Yoder Joe USGR;	May 2008	Complete